**Study Title:** An Adaptive Phase I/II Randomized Placebo-Controlled Trial to Determine Safety, Immunogenicity, and Efficacy of Non-Replicating ChAdOx1 SARS-CoV-2 Vaccine in South African Adults Living Without HIV; and Safety and Immunogenicity in Adults Living with HIV.

**Trial Identifier:** ChAdOx1 nCoV-19\_ZA\_phI/II

**Trial Registration:** ClinicalTrials.gov: NCT04444674; Pan African Clinical Trial Registry: PACTR202006922165132

**Principal Investigators:** Professor Shabir A. Madhi (South Africa) and Professor Andrew Pollard (UK)

**Sponsor:** University of Oxford

**Funders:** UK Research and Innovation (Vaccine supply only), The Bill and Melinda Gates Foundation, and South African Medical Research Council

**Study Design:** This is a double-blinded, randomized, placebo-controlled, multi-center trial designed to assess the safety, immunogenicity, and efficacy of the ChAdOx1 nCoV-19 vaccine in healthy adults aged 18-65 years living with and without HIV. The trial includes four main groups:

1. Group 1 (n=70): HIV-uninfected adults for intensive safety and immunogenicity follow-up.
2. Group 2a (n=250) and 2b (n=1650): HIV-uninfected adults for extended safety, immunogenicity, and vaccine efficacy follow-up.
3. Group 3 (n=100): Adults living with HIV for intensive safety and immunogenicity follow-up.

**Objectives:**

* Primary Objective (Groups 1 and 2): Assess the safety, tolerability, and reactogenicity of the ChAdOx1 nCoV-19 vaccine in healthy HIV-uninfected adults.
* Co-Primary Objective (Group 2): Assess the efficacy of ChAdOx1 nCoV-19 against PCR-confirmed COVID-19 disease in participants who were COVID-19 naive at the time of randomization and received two doses of ChAdOx1 nCoV-19 or placebo.
* Secondary Objective (Group 2): Assess the immunogenicity of ChAdOx1 nCoV-19 in healthy HIV-uninfected adults.
* Primary Co-Objectives (Group 3): Assess the safety and immunogenicity of ChAdOx1 nCoV-19 in adults living with HIV.

**Planned Sample Size:** 2070 participants, with a possible upward adjustment for efficacy endpoints.

**Planned Trial Duration:** Regular visits from enrollment through at least 12 months later.

<https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(21)00157-0/fulltext>